

REMARKS

In the Office Action dated February 25, 2009, claims 15-17 and 19 were objected to because of informalities therein. Those claims have been amended, and the informalities are believed to have been corrected.

Claims 14-17 and 19-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ujhelyi et al in view of Levine.

Applicants note with appreciation the telephone interview courteously afforded the undersigned representative of the Applicants on April 15, 2009, wherein this rejection was discussed. The amendments to claim 14 that are made herein were also discussed at the interview, and it was agreed in the interview that amending claim 14 in this manner would overcome the aforementioned rejection, for the reasons discussed below. The Examiner also stated in the interview that making these changes at this stage of prosecution, after the final rejection, would raise a new issue requiring further searching or consideration, and therefore it would be necessary to file an RCE in order to have such an amendment to claim 14 be entered and considered. The present RCE therefore has been filed.

Claim 14 and claims 16, 17 and 19-29 depending therefrom are submitted to be patentable over the teachings of Ujhelyi et al and Levine, for the following reasons.

As explained in the introductory portion of the present specification, the present invention is based on the recognition that, after delivery of a high-energy shock such as for cardioversion or defibrillation, the threshold necessary for capture may be significantly different (i.e., elevated) than is the

case during “normal” pacing under non-emergency conditions. Therefore, if a pacing mode that includes an autocapture routine is initiated immediately following the delivery of a high-energy shock, this can result in the pacing threshold being set, at least temporarily, at a higher level that will remain until implementation of the next threshold search in the autocapture routine. Moreover, the delivery of the cardioversion shock can temporarily impair the ability of the sensing circuitry to accurately sense intrinsic cardiac activity.

In accordance with the present invention, therefore, after delivery of a high energy shock, the control unit of the pacemaker operates the pulse generator in a fixed pacing mode, with fixed and unchanging settings, until the control unit determines that reversion to the first mode of pacing, that include implementation of an autocapture routine, will be unaffected by the previous delivery of the high energy shock. During the time following the delivery of a high energy shock, the control unit monitors the sensed intrinsic cardiac activity and determines therefrom when reversion to the first mode of operation is unaffected by the delivery of the shock.

Independent claim 14 was among the claims rejected under 35 U.S.C. §103(a) as being unpatentable over Ujhelyi et al. in view of Levine. The Ujhelyi et al. reference discloses pacing under “normal” conditions according to a first mode, which may be a DDD mode. The Ujhelyi et al. reference does not disclose that this first pacing mode may include an autocapture routine, and the Examiner relied on the Levine reference as providing a teaching that it would be conventional to include such an autocapture routine in such “normal” pacing.

Neither the Ujhelyi et al. reference nor the Levine reference, however, provides any teaching whatsoever as to timing the resumption of operation according to the “normal” pacing mode, that include the autocapture routine, following the delivery of a pacing shock. Applicants acknowledge that the Ujhelyi et al. reference discloses that reversion to the “normal” mode of pacing may be delayed, under certain circumstances, while one or more of the loops shown in Figure 2 is executed, but none of those loops is in any way tied to a determination that it is safe or meaningful to revert to the use of the autocapture mode.

Moreover, in the subject matter of claim 14, the second mode of operation, according to fixed parameters, employs parameters that were used prior to delivery of the high energy shock, which means it is not a pacing mode that is artificially created after the delivery of the high energy shock, as in step 208 of the Ujhelyi et al. reference. This is supported in the substitute specification as indicated in paragraphs [0017] through [0019] of the published application.

The only step in Figure 2 of the Ujhelyi et al. patent wherein such pacing might occur is step 212, wherein pacing can either be in a rate-responsive DDD mode (which thus would not be according to "fixed" settings), or at a preprogrammed pacing rate, as stated at column 5, line 39. In either case, the time that pacing takes place in step 212 is completely unrelated to whether and if it is safe and meaningful to resume the use of the autocapture mode, but is instead undertaken until another AF episode is detected in step 214.

In view of the agreements reached in the interview, Applicants submit that claims 14-17 and 19-29 are allowable over the prior art of record. Early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

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